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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,853	11/17/2000	Ashvin H. Desai	10284-0269451	8968

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/715,853	<b>Applicant(s)</b> DESAI, ASHVIN H.	
	<b>Examiner</b> Kathryn Odland	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 10, 15, 17, 20, 21, 24, 25, 30, 33 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 15, 17, 20, 21, 24, 25, 30, 33, and 37-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment/RCE***

This is a response to the Amendment/RCE dated May 19, 2004. Claims 1, 10, 15, 17, 20, 21, 24, 25, 30, 33, and 37-42 are under consideration.

### ***Response to Arguments***

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 10, 15, 17, 20, 21, 24, 25, 30, 33, 37-39, 41, and 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in US Patent No. 5,472,441.

Regarding claim 1, Edwards et al. disclose a method for treating a localized portion of body tissue via inserting a needle apparatus in a body, the apparatus including at least one hollow needle core for delivering a an electrically conductive substance into the body in the form of a gel, whereby the substance is limited to a localized portion of body tissue, as recited in column 7, lines 45-55, column 8, lines 55-65, column 9, lines 22-25, column 10, lines 1-15, column 13, column 16, column 17, lines 1-5 and column 18, lines 5-13. Further, applicant is directed to column 16, lines 15-20 where the electrically conductive solution is discussed. Regarding the phrase, "in

the form of a gel or of microspheres," applicant's disclosure has not established a degree of viscosity for the term "gel." Thus, the solution of Edwards et al. is considered a gel as claimed.

Further Edwards et al. recite guiding the needle apparatus to a desired volume tissue in need of treatment, as recited in column 6, lines 55-65 and column 7, lines 50-55; applying the substance to the volume of tissue through the needle apparatus; determining that the volume of tissue is penetrated by the substance, as discussed throughout the disclosure; and applying RF energy to the substance through an RF electrode to ablate the volume of tissue, where the substance serves an electrode extension conducting the RF energy throughout the volume, as recited throughout the disclosure with emphasis on columns 15-16.

However, Edwards et al. do not explicitly recite a non-invasive imaging technique. On the other hand, non-invasive imaging techniques such as MRI, ultrasound, etc. are extremely well known in the art. Thus, it would be obvious to one with ordinary skill in the art to use a non-invasive imaging technique for the purpose of reducing trauma due to invasion. Further, given this modification the method would include determining that the volume of tissue is penetrated by the substance.

Regarding claim 10, Edwards et al. as modified disclose that as applied to claim 1 as well as a needle apparatus that includes a biopsy needle guide through which the hollow core needle is inserted and the hollow core needle functions as the RF electrode; as recited in columns 13, 15, 16, etc.

Regarding claim 15, Edwards et al. as modified disclose that as applied to claim 1 as well as the use of imaging contrasting agents, as recited in column 17, lines 1-4.

Therefore, it is within the scope of the modification to use imaging contrast agents to for use in determining the volume of tissue penetrated. Further, applicant claims gel and microspheres. Thus, the solution/gel of Edwards et al. is considered an equivalent to microspheres. Moreover, Edwards et al. recite the use of microspheres in column 16. Therefore, it would be obvious and within the scope of the invention to also use microspheres for the conductive solution.

Regarding claim 17, Edwards et al. as modified disclose that as applied to claim 1 as well as necrosing agents and the use of RF in addition to necrosing agents, as recited in column 10, lines 55-58 and column 11.

Regarding claim 20, Edwards et al. as modified disclose that as applied to claim 1. Further, applicant claims gel and microspheres. Thus, the solution/gel of Edwards et al. is considered an equivalent to microspheres. Moreover, Edwards et al. recite the use of microspheres in column 16. Therefore, it would be obvious and within the scope of the invention to also use microspheres for the conductive solution. Thus, it is within the scope of the invention and obvious to one with ordinary skill in the art to use gel and/or microspheres for providing image enhancement when the imaging technique is ultrasound, as recited in column 16 and column 17, lines 1-5. Given the claim does limit

the imaging to ultrasound, when ultrasound is used the liquid would provide image enhancement.

Regarding claim 21, Edwards et al. as modified disclose that as applied to claim 1 as well as a target tissue that is in a prostate and wherein the method is for treating a condition selected from the group of BPH and prostate cancer and is accomplished by a method selected from the group of Transrectal, Transurethral and Transperineal approach, as recited in column 6, lines 60-63 and 08/148,441 which is incorporated by reference in column 1, line 11 (a copy has been provided).

Regarding claim 24, Edwards et al. as modified disclose that as applied to claim 1 as well as the method applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast; as recited in column 4, line 14.

Regarding claim 25 Edwards et al. as modified disclose that as applied to claim 24 as well as inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic, and endoscopic, as recited in column 6, lines 55-65.

Regarding claim 30, Edwards et al. as modified disclose that as applied to claim 1 as well as guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, MRI, CT scan, and ultrasound imaging apparatus, as recited in column 6, lines 55-65.

Regarding claim 33, Edwards et al. as modified disclose that as applied to claim 1 as well as inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout.

Regarding claim 37, Edwards et al. as modified disclose that as applied to claim 1 as well as chemo agents such as tissue necrosing agents, as recited in column 11. Further, binding agents would be obvious if not inherent.

Regarding claim 38, Edwards et al. as modified disclose that as applied to claim 1 as well as microspheres that have a gas (some air inclusion is inherent). However, the solution/gel of Edwards et al. is considered an equivalent to microspheres. Moreover, Edwards et al. recite the use of microspheres in column 16. Therefore, it would be obvious and within the scope of the invention to also use microspheres for the conductive solution.

Regarding claim 39, Edwards et al. as modified disclose that as applied to claim 38 as well as a gas that is selected from the group of *air*, helium, fluorocarbon, and carbon dioxide. However, the solution/gel of Edwards et al. is considered an equivalent to microspheres. Moreover, Edwards et al. recite the use of microspheres in column 16.

Therefore, it would be obvious and within the scope of the invention to also use microspheres for the conductive solution.

Regarding claim 41, Edwards et al. as modified disclose that as applied to claim 10 as well as a conductive component that is selected from the group consisting of conductive polymers, conductive agents, conductive elements, conductive particles and metallic suspensions, as recited in column 16, line 16.

Regarding claim 41, Edwards et al. as modified disclose that as applied to claim 1. The solution/gel of Edwards et al. is considered an equivalent to microspheres. Moreover, Edwards et al. recite the use of microspheres in column 16. Therefore, it would be obvious and within the scope of the invention to also use microspheres for the conductive solution. This modification would necessarily include the conductive gel within a biodegradable container. Biodegradable containers are discussed in column 16, lines 47-50. Nonetheless, the solution gel is considered and equivalent to microspheres.

4. Claims 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in US Patent No. 5,472,441 in view of Barker et al. in JP 405078237. Edwards et al. as modified disclose that as applied to claim 1 as stated above. However, Edwards et al. do not explicitly recite a treatment substance having a binding agent and that binding agent is selected from the group of biomaterial, polymer,



biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil. On the other hand, Barker et al. teach a treatment substance that is in the form of a gel and a gel wherein the gel further has a binding agent and that binding agent is selected from the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil, as stated in the purpose and constitution. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Edwards et al. to use a gel for the purpose of increasing viscosity allowing more controlled delivery.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,231,591 in view of Unger et al. in US Patent No. 5,542,935.

Although the conflicting claims are not identical, the claims of the current application are broader in some respects and more specific in others. The claims of U.S. Patent No. 6,461,296 do not recite a treatment that is a microsphere. On the other hand, Unger et al. teach of therapeutic drug delivery via microspheres, as stated in the abstract. Therefore, it would also be obvious to incorporate microspheres for the purpose of timed/controlled release.

Further, there is recitation of non-invasive imaging and necrosis.

7. Claims 37 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9, 20, 21 and 23 of U.S. Patent No. 10/274,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while a slightly more narrow in others.

8. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/ 300,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while a slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 10/ 265,209. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while a slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

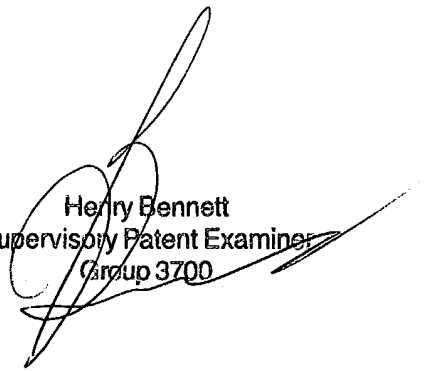
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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